K103231

Tab 5
PREMARKET NOTIFICATION [510(k)] SUMMARY

Summary Date	January 10, 2011 JAN 24 2011
Trade Name:	Kyphon® Inflation Syringe
Common Name:	Arthroscope Tamp
Classification Name:	Class II, Arthroscope, 21 CFR 888.1110 Class I, Orthopedic Manual Surgical Instrument, 21 CFR 888.4540
Device Code:	HRX HXG
Manufacturer's Name:	Medtronic Spine LLC
Address:	1221 Crossman Avenue Sunnyvale, CA 94089
Contact Person:	Hetal Jawahar Thakker
Title:	Sr Regulatory Affairs Specialist
Address:	1221 Crossman Avenue Sunnyvale, CA 94089
Phone:	(408) 548-5334
Predicate Device(s):	Atrion Medical QL® Inflation Device: K032840 (cleared on March 03, 2004)
Intended Use	The Kyphon® Inflation Syringe is intended to be used to inflate and deflate inflatable devices (including Inflatable Bone Tamps) and to measure the pressure within the inflatable device during the procedure.
Device Description:	The Kyphon® Inflation Syringe consists of a syringe barrel; a threaded plunger assembly with a depress-release handle; a digital display that provides pressure readout; an outer shell assembly that retains the internal components; a flexible tubing designed to withstand high inflation pressures; and a weighted swivel-luer for connection to the inflatable device (including Inflatable Bone Tamps). The device is designed to generate and monitor pressures up to 700psi (providing the user the option to be able to select the Maximum Inflation Pressure of 400psi or 700psi depending on the inflatable device being used).

The Locking Syringe (to be packaged together with the Inflation Syringe) is a 30ml polycarbonate syringe and is included for preparation of the inflatable device, as necessary.

A V-Klip™ (available as part of the 2 Pack configuration) holds two Kyphon Inflation Syringes for concurrent dual-syringe operation.

Testing

Testing of the Kyphon® Inflation Syringe was completed to demonstrate that the device meets the specifications and performance characteristics, and is substantially equivalent to the predicate devices. The testing included functional and mechanical testing. In addition, biocompatibility testing and sterilization validation were completed.

Biocompatibility

Biocompatibility testing of the Kyphon® Inflation Syringe confirmed that the devices meet applicable requirements of the FDA Blue Book Memorandum #G95-1 entitled "Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing" and are biocompatible.

Sterilization

The Kyphon® Inflation Syringe will be provided sterile and is intended for single use only.

Packaging and Labeling

The components are placed in an inner and outer polyethylene terephthalate glycol (PETG) Tray with a Tray lid. This configuration is sealed with a Tyvek® Lid, and placed in a carton.

Substantial Equivalence:

The information submitted in this pre-market notification supports a determination that the Kyphon® Inflation Syringe is substantially equivalent to the predicate devices, the Atrion Medical QL Inflation Device cleared under K032840. The products have the same fundamental scientific technology and basic design, and similar intended use and functional characteristics as the predicate Inflation Syringe.
The results of testing demonstrate that the Kyphon® Inflation Syringe is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Medtronic Spine, LLC
% Hetal Jawahar Thakker
Senior Regulatory Affairs Specialist
1211 Crossman Avenue
Sunnyvale, California 94089

JAN 24 2011

Re: K103231
Trade/Device Name: Kyphon® Inflation Syringe
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX, HXG
Dated: October 29, 2010
Received: November 1, 2010

Dear Hetal Jawahar Thakker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

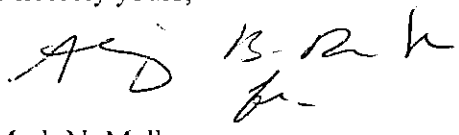
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Tab 4

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): _____

Device Name: Kyphon® Inflation Syringe

Indications for Use:

The **Kyphon® Inflation Syringe** is intended to be used to inflate and deflate inflatable devices (including Inflatable Bone Tamps) and to measure the pressure within the inflatable device during the procedure.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103231